

# PATENT COOPERATION TREATY

# PCT


# Re PCT/PTO 15 SEP 2005

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

10/549290

Applicant's or agent's file reference 150372/KB		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/CZ2004/000017		International filing date (day/month/year) 30.03.2004		Priority date (day/month/year) 31.03.2003
International Patent Classification (IPC) or national classification and IPC A61K31/282				
Applicant PLIVA-LACHEMA A.S. et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  23.10.2004		Date of completion of this report  17.06.2005		
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Friederich, M  Telephone No. +49 89 2399-7860		



INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITYInternational application No.  
PCT/CZ2004/000017

10/549296

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-19 as originally filed

**Claims, Numbers**

1-19 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
  - ☐ the claims, Nos.
  - ☐ the drawings, sheets/figs
  - ☐ the sequence listing (*specify*):
  - ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT  
ON PATENTABILITY**

International application No.  
PCT/CZ2004/000017

---

**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

---

1. Statement

Novelty (N)	Yes: Claims	1-19
	No: Claims	
Inventive step (IS)	Yes: Claims	1-19
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-19
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

**Re Item V**

**Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

- D1: US-A-6 136 336 (KUWAHARA ETSUHISA ET AL) 24 October 2000 (2000-10-24)  
D2: WO 99/61451 A (MISTR ADOLF ; LACHEMA AS (CZ); M & ECARON (CZ);  
POULOVA ANNA (CZ); ZAL) 2 December 1999 (1999-12-02)

If not indicated otherwise, the relevant passages are those mentioned in the International search report.

**Art. 33(2)** The present application meets the requirements of Article 33(2) PCT, because the subject-matter of **claims 1-19** appears to be new in the sense of Article 33(2) PCT.

The prior art cited in the search report does not disclose a pharmaceutical composition comprising the claimed compounds, a neutral saccharide and a modified polysaccharide in granules having a particle size below 0,5mm.

**Art. 33(3)** The subject-matter of **claims 1-19** is considered to involve an inventive step in the sense of Article 33(3) PCT.

D2 discloses pharmaceutical compositions comprising platinum complexes according to the present application from which the subject-matter of

**claims 1-19** differs in that no inclusion complexes with cyclodextrins are used (see the description of the present application, page 2, first paragraph).

The problem to be solved by the present invention may therefore be regarded as how to provide stable solid dosage formes of the claimed platinum complexes having a good solubility (see the description of the present application, page 2, second paragraph).

The present application suggests to solve the problem posed by granulating the active compounds with a neutral saccharide and a modified polysaccharide.

D1 discloses suppositories comprising amorphous satraplatin.

There is no indication in the prior art documents that a composition obtainable by wet granulation and comprising the claimed combination of satraplatin, a neutral saccharide and a native/modified polysaccharide would solve the posed problem as it has been shown in the present application (see examples 26-28).

It is therefore noted, that the solution proposed in **claims 1-19** of the present application is considered to be inventive in the sense of Article 33(3) PCT.

**Art. 33(4)** The subject-matter of **claims 1-19** is considered to be industrially applicable in the sense of Art. 33(4) PCT.